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07/29/2003

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EXAMINER

FALK, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

19

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/353,423

Applicant(s)

NAGABHUSHAN ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-9, 19-34 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 19-34 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The amendment filed May 8, 2003 (Paper No. 18) has been entered. Claim 34 has been amended.

Accordingly, Claims 1-4, 7-9, 19-34, and 36-39 remain pending in the instant application.

The following rejections are reiterated and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 8, 2003 (Paper No. 18) has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7-9, 19-34, and 36-39 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 2-9 of the Office Action of Paper No. 5 (mailed 10/4/00) and on pages 2-7 of Paper No. 9 (mailed 8/2/01) as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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At pages 3-4 of the response, Applicants argue that the law does not require that Applicants describe in detail how to practice the claimed invention because all that is required is to provide enough information to one of skill in the art, analogous to what Applicants characterize as “pointing the fisherman to general vicinity of the fish.” However, the courts have made it clear that, while it is not necessary to include information that is already well known in the art, it is not to be left up to the skilled artisan to figure out how to make the necessary starting materials and then to figure out how to use them to produce the biological effects as recited in the claims. The courts held that the disclosure of an application shall inform those skilled in the art how to use applicant’s claimed invention, not how to **find out** how to use it for themselves. *In re Gardner et al.* 166 USPQ 138 (CCPA 1970). This specification only teaches what is intended to be done and how it is intended to work, but does not actually teach how to do that which is intended.

At pages 5-7 of the response, Applicants assert that the skilled artisan would be able to employ the vectors of the present invention in their broadest scope without additional teachings beyond that provided by the specification because, Applicants reason, one of skill in the field of gene therapy has an exceptionally high level of expertise. Applicants argue that the ordinarily skilled artisan in this field has at least an M.D. degree and performs gene therapy clinical trials at a major university teaching hospital or prominent clinical institution. While the Examiner acknowledges that those performing gene therapy clinical trials have an exceptionally high level of expertise, and would certainly be included as “one of skill in the art,” it is rare that such individuals engage in routine experimentation to implement established gene therapy protocols. On the contrary, such individuals are generally involved in ground-breaking research, and would not be considered one of ordinary skill in the art, but rather would be considered one of exceptional skill in the art.

At pages 7-8 of the response, Applicants argue that there is a large volume of NIH-approved clinical investigations with recombinant viral vectors. Applicants conclude that this is evidence of the

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ability of those of skill in the art to practice gene therapy protocols. However, the existence of a wide variety of clinical trials is not an indicator that gene therapy is a predictable art. On the contrary, successful gene therapy protocols have been developed only with painstaking effort and intensive investigation.

At pages 8-9 of the response, Applicants argue that the immune response to adenoviral vectors is not the barrier to therapeutic effect as was speculated. Applicants further argue that the references cited by the Examiner "are obsolete in view of current clinical experience." As a reminder, it is noted that the priority date of this application is October 1996. Three of the articles cited to support unpredictability in the art were published in 1997 and one was published in 1998. Thus, the cited references are clearly representative of the state of the art at the time the invention was made. Applicants have not offered any support for their suggestion that the references are obsolete. Applicants point to several articles published in 2002 and 2003, which discuss repeat dosing of adenoviral vectors. However, these are post-filing references and are not representative of the state of the art at the time the invention was made. As such, the skilled artisan would not have had the benefit of the additional teachings provided in these references.

At page 10 of the response, Applicants again argue that the law does not require human clinical data to demonstrate efficacy. The Examiner has not suggested that human clinical data is required.

The court has recognized that physiological activity is unpredictable. *In re Fisher*, 166 USPQ 18 (CCPA 1970). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved. *In re Fisher*, 166 USPQ 18 (CCPA 1970).

In the instant case, it is clear that further experimentation is required to allow the skilled artisan to practice the claimed invention and use the claimed compositions *in vivo*. Given that the state of the art is unpredictable, for reasons of record, the skilled artisan would have been required to engage in undue experimentation to practice the claimed invention *in vivo* and achieve the claimed result.

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Given the limited working examples, the limited guidance in the specification, the broad scope of the claims, and the unpredictability of using the claimed methods and compositions *in vivo*, undue experimentation would have been required for one skilled in the art to practice the claimed methods *in vivo*.

Conclusion

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER